## IN THE UNITED STATES RECEIVING OFFICE

| International Application Number | International Filing Date | International Earliest Priority Date |  |
|----------------------------------|---------------------------|--------------------------------------|--|
| PCT/CA2003/001069                | 16 July 2003              | 16 July 2002                         |  |
|                                  | 16.07.03                  | 16.07.02                             |  |

TITLE OF INVENTION:

COMPOSITION FOR CYTOCOMPATIBLE, INJECTABLE, SELF-

GELLING CHITOSAN SOLUTIONS FOR ENCAPSULATING AND DELIVERING LIVE CELLS OR BIOLOGICALLY ACTIVE

**FACTORS** 

APPLICANT FOR DO/US:

BIO SYNTECH CANADA, INC.

**INVENTORS FOR DO/US:** 

HOEMANN, Caroline; CHENITE, Abdellatif; BUSCHMAN,

Michael; SERREQI, Alessio; and SUN, Jun

U.S. SERIAL NO.:

10/521,524

## **CERTIFICATE OF MAILING**

I hereby certify that this correspondence, on the date shown below, is being deposited with the United States Postal Service with sufficient postage as Express Mail Label No. EV653001477US in an envelope addressed to MAIL STOP PCT, Commissioner of Patents, Box 1450, Afexandrian VA 2231371450.

Date: September 2005

inda M. Ginsberg

MAIL STOP PCT Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450

Sir/Madam:

#### INFORMATION DISCLOSURE STATEMENT

In accordance with the provisions of 37 C.F.R. §1.56, 1.97, and 1.98, Applicants wish to bring to the Examiner's attention the following references, References A1-A3, B1-B5 and C1-C11 cited in the attached Forms PTO/SB/08a and b.

## **REMARKS**

In accordance with the provisions of 37 C.F.R. §1.97, this statement is being filed:

(1) within three (3) months of the Filing Date or before the mailing date of the First Office Action on the merits; or

(2) within three months of the mailing date of the PCT International Search Report; or

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(3) after the period defined in (1) but before the mailing date of a Final
Rejection or Notice of Allowance, and the requisite Certification or fee
under Rule 1.17(p), namely \$180.00, is included herein; or

(4) after the mailing date of a Final Rejection or Notice of Allowance but
before the payment of the Issue Fee, and the requisite Certification, petition,
and petition fee are included herein.

X
A copy of the International Search Report is enclosed herewith.

It is respectfully requested that each of the documents shown on the attached form(s)
PTO/SB/08a and b be made of record in this application.

Copies of these documents (CHECK ONE):

\_X are enclosed herewith that have not been previously submitted; or

have been cited in the parent application, and are thus not being resubmitted herein.

#### FEE AUTHORIZATION

The Commissioner is authorized to charge fee deficiencies or credit overpayments associated with this submission to the NIXON PEABODY LLP Deposit Account No. 50-0850.

Date: September 20, 2005

Respectfully submitted,

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Complete i

10/521,5

16 July 2003

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Substitute for form 1449A/PTO

# INFORMATION DISCLOSURE STATEMENT BY APPLICANT

|                                   |          |    |     | First Named Inventor Caroline Hoemann |                |
|-----------------------------------|----------|----|-----|---------------------------------------|----------------|
| (use as many sheets as necessary) |          |    |     | Art Unit                              | To be assigned |
|                                   | <u> </u> |    |     | Examiner Name                         | To be assigned |
| Sheet                             | 1        | of | 2 . | Attorney Docket Number                | 701826-56360   |

I.A. Filing Date

Application Number

|                      |                          |  | U.S. PATENT DO                 | CUMENTS  |  |
|----------------------|--------------------------|--|--------------------------------|--|--|
| Examiner<br>Initials | Cite<br>No. <sup>1</sup> | U.S. Patent Document  Number - Kind Code <sup>2</sup> (if known) | Publication Date<br>MM-DD-YYYY | Name of Patentee or<br>Applicant of Cited Document | Pages, Columns, Lines, Where Relevant<br>Passages or Relevant Figures Appear |
|                      | A1                       | US-4,895,724   | 01/23/1990                     | Cardinal et al.                                    |  |
|                      | A2                       | US-5,489,401   | 02/06/1996                     | Freeman  |  |
|                      | A3                       | US-5,871,985   | 02/16/1999                     | Aebischer et al.                                   |  |
|                      |                          | US-  |                                |  |  |

|                      |              | FC   | PREIGN PATENT                  | DOCUMENTS  | ······································  |                |
|----------------------|--------------|--|--------------------------------|--|---|----------------|
| Examiner<br>Initials | Cite<br>No.1 | Foreign Patent Document  Kind Code <sup>3</sup> Country Code <sup>3</sup> Number <sup>4</sup> (if known) | Publication Date<br>MM-DD-YYYY | Name of Patentee or<br>Applicant of Cited Document | Pages, Columns, Lines, Where<br>Relevant Passages or Relevant<br>Figures Appear | T <sup>6</sup> |
|                      | Bl           | WO 99/07416 A1   | 02/18/1999                     | Chenite, Abdellatif et al.                         |   |                |
|                      | B2           | WO 99/47186 A1   | 09/23/1999                     | Suh, Jun-Kyo et al.                                |   |                |
|                      | B3           | WO 02/00272 A2   | 01/03/2002                     | Hoemann, Caroline et al.                           |   |                |
|                      | B4           | WO 02/40070 A2   | 05/23/2002                     | Desrosiers, Eric et al.                            |   |                |
|                      | B5           | WO 03/042250 A1  | 05/22/2003                     | Chenite, Abdellatif et al.                         |   |                |
|                      |              |  |                                |  |   |                |
|                      |              |  |                                |  |   |                |
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|                      |              |  |                                |  | · .   |                |

| Examiner  | Date       |  |
|-----------|------------|--|
| Signature | Considered |  |

<sup>\*</sup>EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

Applicant's unique citation designation number (optional). <sup>2</sup> See Kinds Codes of USPTO Patent Documents at 222.uspto.gov or MPEP 901.04. <sup>3</sup> Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). <sup>4</sup> For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. <sup>5</sup> Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. <sup>6</sup> Applicant is to place a check mark here if English language Translation is attached.

| Substitute for form 1449A/PTO INFORMATION DISCLOSURE STATEMENT BY APPLICANT |                                   |      |            | Complete i wn          |                  |  |
|---|-----------------------------------|------|------------|------------------------|------------------|--|
|   |                                   |      | OSURE      | Application Number     | 10/521,52-       |  |
|   |                                   |      |            | I.A. Filing Date       | 16 July 2003     |  |
| SIA.  | •                                 |      |            | First Named Inventor   | Caroline Hoemann |  |
|   | (use as many sheets as necessary) |      | Art Unit . | To be assigned         |                  |  |
|   |                                   |      |            | Examiner Name          | To be assigned   |  |
| Sheet   | 2                                 | of . | 2          | Attorney Docket Number | 701826-56360     |  |

|                       |              | OTHER PRIOR ART – NON PATENT LITERATURE DOCUMENTS  |                |
|-----------------------|--------------|--|----------------|
| Examiner<br>Initials* | Cite<br>No.1 | Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.)., date, page(s), volume-issue number(s), publisher, city and/or country where published. | T <sup>2</sup> |
|                       | C1           | CAPITANI, D. et al.; Carbohydrate Polymers; 45:245-252 (2001)  |                |
|                       | C2           | DE ANGELIS, A.A. et al.; Macromolecules; 31:1595-1601 (1998)   |                |
|                       | C3           | HSIEN, T.Y. and RORRER G.L.; Ind. Eng. Chem. Res.; 36:3631-3638 (1997)   |                |
|                       | C4           | KUMBAR S.G. et al.; J. Microencapsulation; 19(2):173-180 (2002)  |                |
| *                     | C5           | LI, J. et al.; Journal of Pharmaceutical Sciences; 91(7):1669-1677 (2002)  |                |
|                       | C6           | MI, FL. et al.; Biomaterials; 23:181-191 (2002)  |                |
|                       | . C7         | MONTEIRO, JR., Oyrton A.C. et al.; International Journal of Biological Macromolecules; 26:119-128 (1999)   |                |
|                       | C8           | ROGOVINA, S.Z. et al., Polymer Science, 43(9-10):265-268 (2001)  |                |
| ··                    | C9           | RUEL-GARIEPY, E. et al.; International Journal of Pharmaceutics; 203:89-98 (2000)  |                |
|                       | C10          | SUH, J.K Francis et al.; Biomaterials; 21:2589-2598 (2000)   |                |
|                       | C11          | SUTO, Shinichi et al., Journal of Applied Polymer Science; 61:2273-2278 (1996)   |                |

| Examiner  | Date       |   |
|-----------|------------|---|
| Signature | Considered | · |

<sup>\*</sup> EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

<sup>&</sup>lt;sup>1</sup> Applicant's unique citation designation number (optional). <sup>2</sup> Applicant is to place a check mark here if English language Translation is attached.